

Exhibit F

1 Q Any documents in there specifically that you remember
2 reading front to back?

3 A At this -- well, the IFU is in there, so I have read that
4 in the past front to back. I read the historical
5 documents about how TVT first was developed. And those
6 are the ones that I remember in particular. There are a
7 couple PowerPoint presentations that I probably was in --
8 present for or were delivered to me.

9 Q Doctor, how many of these -- how many of these 34
10 documents do you think you actually reviewed in full?

11 MR. KOOPMANN: Object to form.

12 THE WITNESS: I can't give you an
13 exact answer to that, but if you look through it, they're
14 historical documents, so I don't -- I didn't spend much
15 time at all with the Internet discussions between the
16 Ethicon people and the corporation.

17 Q (By Mr. DeGreeff) Did you -- in rendering your opinions,
18 did you rely at all on internal company documents?

19 A No.

20 Q Why not?

21 A I don't find them necessarily relevant.

22 Q Why are they not relevant?

23 A Well, because a lot of it has to do with research and
24 development early on in the development of the products,
25 and quite frankly, it's not -- I don't find it relevant

1 for me in rendering an opinion.

2 Q Did you review any of the design documents for the
3 product?

4 MR. KOOPMANN: Objection. Form.

5 THE WITNESS: I don't recall design
6 documents. You mean the original design of the -- of the
7 mesh?

8 Q (By Mr. DeGreeff) Yeah, the design documents, the
9 internal design documents for the mesh product?

10 A Well, if you could show me one, I could tell you whether
11 I've reviewed it or not.

12 Q Well, do you know what I'm talking about when I say
13 design documents?

14 A Not precisely, no.

15 Q Okay.

16 A Are you talking about before it was submitted to the FDA?

17 Q Well, have you reviewed the design device file?

18 MR. KOOPMANN: Objection. Form.

19 THE WITNESS: I don't recall.

20 Q (By Mr. DeGreeff) As you sit here, do you remember
21 recalling any -- reviewing any internal Ethicon documents
22 specifically relating to design of the TVT products?

23 A I'm sure I've looked at several, but none come to mind
24 specifically.

25 Q Okay. If you think you looked at several, what did those

1 documents look like? What did they tell you?

2 A Oh, I don't recall. I looked at them prior to the Perry
3 trial, I would imagine.

4 Q Okay. So -- and the Perry trial was about the TVT
5 Abbrevio; correct?

6 A Correct.

7 Q And we're not here -- you're not rendering any opinions
8 in this -- at this point generally about the TVT Abbrevio?

9 A No.

10 Q So my question is about design documents that would be
11 relevant to the products that we're here about. Do you
12 remember reviewing any of those design documents?

13 A Not specifically.

14 Q Well, not specifically. Do you remember reviewing any at
15 all?

16 A If you put one in front of me, I can tell you whether I
17 have or not.

18 Q Well, Doctor, you've got them -- are they on your
19 reliance list?

20 A Some may be.

21 Q And did you review everything on your reliance list?

22 A I've -- in a general sense, yes. Specifically, I mean,
23 there's a lot of documents, and some I may have just
24 looked at the title and then what the conclusions were,
25 and if something was interesting in there, I would go

1 Q Did defense counsel select the documents that went into
2 that binder?

3 A Yes.

4 Q Have you reviewed all of the documents in that binder?

5 A Well, I've reviewed them -- a lot of them I've reviewed
6 before they ever were put in the binder, before I was
7 ever asked to review them.

8 Q Okay. So my question was a little different than that.

9 Have you reviewed -- and I don't care when you
10 reviewed them. Have you reviewed all of the lit- -- all
11 of the documents that are in that binder?

12 A Well, no. The ones I haven't reviewed were the pre-FDA
13 design documents, which are very tedious, and I didn't
14 find relevant.

15 Q So fair to say, you did not review the design documents
16 that were relied on by Ethicon for approval by the FDA?

17 MR. KOOPMANN: Objection to form.

18 THE WITNESS: That's true.

19 Q (By Mr. DeGreeff) Anything else?

20 A Well, there's just a bunch of minutes and discussions by,
21 I guess, engineers within the -- within the company on
22 the product specifications and the launch of the product.

23 Q And did you review those?

24 A I did not.

25 Q Why not?

1 A Well, because I don't find it relevant.

2 Q And that's the -- those are memos done by the engineers
3 who designed the product?

4 A Correct.

5 Q Why did you not find that relevant?

6 A Well, because it's tremendously tedious, and it's not
7 clinically relevant. It was how they developed the
8 product and -- the device, and it's kind of too technical
9 for my interest.

10 Q And you didn't -- so you didn't review that in rendering
11 your opinions?

12 A No.

13 Q Did you review any documents related to the -- kind of
14 the -- what you referred to as the tedious portion of the
15 design of the -- of the document and getting FDA
16 approval?

17 MR. KOOPMANN: Objection. Form.

18 THE WITNESS: There may be a few that
19 I reviewed.

20 Q (By Mr. DeGreeff) Which ones? Any as you sit here that
21 you remember?

22 A My patients' list at home.

23 Q I was wondering how that got in there.

24 A Yeah, that just got -- it fell in.

25 The ones I reviewed were -- see, a lot of this is

1 MR. KOOPMANN: Objection. Form.

2 THE WITNESS: I will say no. I will

3 say, though, that -- that all of us give feedback to the

4 companies that we use mesh, as to what might be better

5 about it.

6 Q (By Mr. DeGreeff) I think we agree. My question is

7 pretty simple. Yes or no, are you holding yourself --

8 yes, no, or you can't answer. Are you holding yourself

9 out as an expert on the design of transvaginal mesh

10 products?

11 MR. KOOPMANN: Objection. Form.

12 Asked and answered.

13 THE WITNESS: Do I answer?

14 MR. KOOPMANN: Go ahead, yeah.

15 THE WITNESS: So I am not a product

16 engineer that has designed mesh products. However, I

17 have used them, and I have opinions about what -- what is

18 good or bad about a particular product, which I have

19 expressed to multiple companies when asked. So -- but I

20 am not an engineer.

21 Q (By Mr. DeGreeff) Let's try this again. Doctor, yes,

22 no, or you cannot answer my question as it's phrased:

23 Are you holding yourself out as an expert in the design

24 of transvaginal mesh products?

25 MR. KOOPMANN: Same objection.

1 THE WITNESS: No, I'm not a design
2 expert.

3 Q (By Mr. DeGreeff) Doctor, one more binder. And I don't
4 know -- let's see. This says --

5 A That's TVT and TVT-O. I think it's -- is it long-term
6 studies? It's a series of studies. Now, some of this is
7 contained in these other binders.

8 Q I was going to ask, this says long-term studies. Does
9 this contain the same ten studies that we talked about
10 earlier?

11 A If you'd hand it to me, I could answer that.

12 MR. DEGREEFF: Sure, I will. Let's
13 mark this. I'll mark this as Deposition Exhibit 11.

14 (Exhibit No. 11 marked for
15 identification.)

16 Q (By Mr. DeGreeff) Have I done so?

17 A Yes.

18 Q And can you tell us the -- before we get started, can you
19 tell us the title of that?

20 A "TVT and TVT-O Long-Term Studies for Experts."

21 Q Why would that be called long-term studies for experts
22 rather than long-term studies for Dr. Grier?

23 A Well, because this series of articles, which are
24 long-term, is probably used by other -- other
25 gynecologists or urologists who have been asked to be

1 not create a foreign body reaction, have you?

2 A No.

3 Q Have you ever authored an article on SUI or incontinence
4 in general?

5 MR. KOOPMANN: Object to the form.

6 THE WITNESS: Well, yes.

7 Q (By Mr. DeGreeff) Which one would that be?

8 A That's the Tincello article that's in here, the TVT World
9 Registry.

10 Q You believe that deals with SUI or incontinence
11 generally?

12 A Oh, well, it's for the treatment of stress incontinence.

13 Q And that was the one that got cut off early?

14 A That was the one that was completed at the one-year mark
15 and published.

16 Q Published in 2014?

17 A That's my memory.

18 Q After the TVT-S was taken off the market?

19 A I don't remember the chronology of which was which, but
20 yeah, that probably is true.

21 Q Doctor, what was the point of publishing the article
22 after the product was removed from the market?

23 A That's the point of science. It's to -- it's an ongoing
24 investigation that -- that's a philosophical question.

25 Q Doctor, you're not an expert on warnings, are you?

1 MR. KOOPMANN: Objection. Form.

2 Q (By Mr. DeGreeff) Medical device warnings?

3 MR. KOOPMANN: Same objection.

4 THE WITNESS: No.

5 Q (By Mr. DeGreeff) You're not a biomedical engineer, are
6 you?

7 A No, I'm not.

8 Q And we've already talked about this, but you're not
9 holding yourself out as an expert on the design of
10 medical devices, are you?

11 MR. KOOPMANN: Objection to form.

12 Asked and answered many times.

13 THE WITNESS: I'm not an expert on it,
14 although I have been using medical devices for my entire
15 career. So I certainly can give opinions on their safety
16 and efficacy.

17 Q (By Mr. DeGreeff) Well, now, giving an opinion on
18 whether you believe a device is safe and effective is
19 different than being able to give an opinion on design;
20 correct?

21 A Yes.

22 Q Are you qualified to give -- you're not holding yourself
23 out as an expert on the area of design, are you?

24 MR. KOOPMANN: Objection to form.

25 THE WITNESS: No.

1 Q (By Mr. DeGreeff) I mean, you've never designed a
2 medical device; correct?

3 A Correct.

4 Q Never been involved in the design of a medical device?

5 A I've been in -- I've been asked to give opinions on
6 devices and -- during their development.

7 Q You don't have any patents on medical devices?

8 A No.

9 Q Doctor, do you know what employees from Ethicon were
10 involved in the design of the TVT?

11 A No. I thought Ulf Ulmsten was the one who designed the
12 TVT.

13 Q Do you know what Ethicon paid Ulf for the product?

14 A No.

15 Q What is MedScan?

16 A I'm not sure. Is that a search engine for medical -- or
17 articles, scientific articles?

18 Q I'm asking you, Doctor. Did Dr. Ulmsten design the mesh
19 used in the TVT?

20 MR. KOOPMANN: Objection. Form.

21 THE WITNESS: My memory is that in the
22 1990s -- and this is coming from his mouth -- he was
23 experimenting with -- he came up, along with a
24 gynecologist from Australia by the name of Petros, of a
25 new and novel integral theory of continence, which was

1 in studies on the inventor's device?

2 A Oh, again, I have no idea. How would I know that
3 information? I've not heard it.

4 Q Do you think they should?

5 A Should prevent? No.

6 Q Do you know whether Ethicon has any policies in place
7 that prohibit inventors from participating in studies on
8 the inventor's device?

9 A I'm not aware.

10 Q Do you think they should?

11 A It's -- I don't have an opinion.

12 Q It doesn't matter to you?

13 A No.

14 Q Doctor, are you aware of how long it took the -- it took
15 Ethicon to get the TVT-O product to market?

16 A I don't recall the timeline.

17 Q Doctor, what is Provencia?

18 A I don't know.

19 Q Do you know what a failure modes and effect analysis is?

20 A That sounds like an engineering design study to look at
21 physical properties of different products/materials.

22 Q Have you ever been involved in one of those analyses?

23 A No.

24 Q What should be in a failure modes and effects analysis?

25 MR. KOOPMANN: Objection. Form.

1 THE WITNESS: Well, can you give me a
2 product or material that you want to apply it to?

3 Q (By Mr. DeGreeff) Mesh. What should be in a failure
4 mode designs effect analysis for mesh?

5 MR. KOOPMANN: Objection. Form.

6 THE WITNESS: Well, one would be what
7 its tensile strength is, elongation overload. Those
8 would be the main ones.

9 Q (By Mr. DeGreeff) Have you ever -- did you review the --
10 any of the FMEAs in this case?

11 A I've seen some, yes.

12 Q For transvaginal mesh?

13 A Uh-huh.

14 Q Which ones?

15 A Oh, I think Guenther is one. Moalli has some. But
16 there's Dietz study from Australia that described the
17 bench loading and elongation.

18 Q You're talking about articles and studies; correct?

19 A Yes. But I -- as far as the -- you mean as far as
20 corporate documents in terms of what they did prior to
21 the product being released?

22 Q Yes.

23 A I would glance over them and not -- and not read them.

24 Q All potential hazards should be in the failure modes
25 effects analysis for TVT; correct?

1 MR. KOOPMANN: Objection. Form.

2 THE WITNESS: Again, I don't know what
3 that means.

4 Q (By Mr. DeGreeff) You don't know what a design failure
5 modes effect analysis is?

6 A Well, I know -- I know what the term is, but when you're
7 saying -- there's a difference between in vivo and ex
8 vivo. If you're talking about bench testing products
9 that the stresses that are put on them are greater than
10 the physiologic stress in the body, I don't think those
11 are relevant.

12 I mean, it's fine to do the studies to get a sense
13 of what the burst strength is of mesh, but it's never
14 going to be seen after it's deployed.

15 Q And you don't find those studies relevant, or those
16 relevant?

17 A Well, it has a relevance, but it doesn't have a high
18 significance.

19 Q You don't find them significant?

20 A It has a significance. I can't -- I'm not going to give
21 you a degree of significance.

22 Q You didn't rely on them in giving your opinions in this
23 case; fair?

24 A Well, when I looked at them, I want to make sure that the
25 stressors of these meshes, after they're deployed in the

1 body, that they're not going to degrade at those -- at
2 those loads. In that regard they're relevant. When
3 you're talking about you're pushing out the load a long
4 way, which is not physiologic, that's not relevant.

5 Q Okay. So I guess my -- I'm not sure that you ever
6 answered my question. As you sit here, do you remember
7 reviewing any of the design failure mode effects analysis
8 for the transvaginal -- the Ethicon transvaginal mesh
9 products in rendering your opinions?

10 A I don't recall specific ones. If you put one in front of
11 me, I can tell you whether I've reviewed it.

12 Q You told me a lot of the documents were in another
13 language. Did you ask for those to be translated?

14 A No.

15 Q As you sit here, you don't remember -- you can't remember
16 reviewing any specific design failure mode effects
17 analysis on -- regarding transvaginal mesh made by
18 Ethicon?

19 A I can't recall a specific one, no.

20 Q Did you review any internal documents discussing how long
21 it took Ethicon to get the TVT-O product to the market?

22 MR. KOOPMANN: Objection. Form.

23 Asked and answered.

24 MR. DEGREEFF: It was?

25 MR. KOOPMANN: I think so.

1 of TVT-Os due to complications; correct?

2 MR. KOOPMANN: Objection. Form.

3 THE WITNESS: I have removed sections

4 of TVT-Os for exposure. I can't remember any for any

5 other reason.

6 Q (By Mr. DeGreeff) And is that something you track?

7 A Oh, I -- well, I track all my patients. I see them -- I

8 try to see them on an annual basis, and if they don't

9 agree, I try to make it every other year.

10 Q So do you have something in your office where you track

11 the reason for each removal and what product it is you're

12 removing?

13 A Their medical records.

14 Q Is that a list you would keep in your office somewhere?

15 A It's one I could retrieve.

16 Q So you have a list currently kept in your office of the

17 product you removed and with -- with the reason for

18 removal?

19 A No, I don't have a list.

20 Q And how many TVT-O removal surgeries have you done?

21 A Well, partial TVT-O, I would say a half dozen maybe.

22 Q What about TVT-R?

23 A Same. About a half dozen.

24 Q What about TVT-S?

25 A Maybe three or four.

1 Q So in your entire time working with transvaginal mesh,
2 between TVT, TVT-O, and TVT-S, you believe you've only
3 done 15 to 16 removal surgeries?

4 A I'm sure I've removed 35, 40 other products that are
5 either transobturator or retropubic slings.

6 Q So you've only done 50 total removal surgeries in your
7 time working with transvaginal mesh?

8 A Do you -- are you including POP repair, like Prolift or
9 elevate, Apogee, Perigee, the other products?

10 Q Well, I was asking specifically about TVT, but sure, we
11 can talk about those too.

12 A I mean, I don't keep numbers of it, but I've removed each
13 of those products in the past.

14 Q That was going to be my question. Where's the tracking
15 data on TVT-Rs that were removed, on the number of
16 explants you've done?

17 A What do you mean by "tracking data"?

18 Q Is that something you keep track of in your office?

19 A No, I don't keep track of the numbers.

20 Q How long have you been doing removal surgeries? When did
21 you first start doing them?

22 A Well, again, when you use the word "removal," I'll take
23 out a specific area that may be exposed, or if there's a
24 specific trigger point area of pain, I'll remove that
25 part.

1 my entire practice was. At that point I was probably
2 seeing one-third males and two-thirds females. But
3 because of the shrinking volume of women who seek care
4 for these problems, I do less and less each year.

5 Q And what percentage of your practice is related to
6 treating TVM complications?

7 A Oh, less than 1 percent.

8 Q What percentage of your practice is related to the
9 surgical treatment of TVM complications?

10 A Oh, I'd say less than 1 percent at this point. I don't
11 see them that often.

12 Q Doctor, do you do anything within your office to track
13 what percentage of the women that you do implants in are
14 lost to follow-up?

15 A No.

16 Q Do you know what the national average is?

17 A No.

18 Q Do you know what the national average is on complications
19 related to following implant surgeries with TVM?

20 A Oh, there's several papers that provide those numbers.

21 Q Certainly greater than 1 percent, isn't it?

22 A I think it's about 3 and a half percent.

23 Q So you believe 3 and a half is the rate?

24 A One recent paper I reviewed, that was the rate of
25 complications that required something to be done.

1 Q Ever seen any others that's different?

2 A Oh, it's all -- it depends on what study and what cohort.

3 If you happen to be a referral center, you're going to

4 see a lot more because a lot of gynecologists aren't

5 comfortable with doing repairs or revisions.

6 Q And a lot of patients aren't comfortable going back to

7 the person who put in an implant that gave them

8 complications; fair?

9 A That's -- complications in general, for all of medicine,

10 a lot of times patients have unrealistic expectations and

11 will go elsewhere when they don't have exactly the

12 outcome that they want. That's very common, not just in

13 this.

14 Q Okay.

15 A It's common with all complications.

16 Q So it's typical for anybody -- any surgeon to have a

17 significant loss to follow-up; is that fair?

18 A It really -- it depends on what community you're in. If

19 there are -- if you're in a smaller community and there's

20 less choices of where to go, a lot of times, if a patient

21 has a complication and doesn't see you, they'll see one

22 of your colleagues, and they'll -- we can discuss it,

23 they'll -- you'll find out about it. There's many a time

24 where I've called a physician to tell them that a patient

25 of theirs came in and this was their concerns.

1 A Yes.

2 Q And again, that's an email that you sent to Lori
3 Campbell?

4 A Yes.

5 Q And why the exclamation mark, Doctor? Were you proud
6 that you'd spent \$104,000 on Ethicon products?

7 A No. Kind of the opposite. I was shocked that I had
8 spent so much money for a product, you know, as far as
9 checks are. It just kind of shocked me that it had been
10 that much.

11 Q Well, was it important to you to be considered a good
12 account?

13 A No. No. It was a realization that the products are
14 expensive.

15 Q When does your -- when you say "this year to date," when
16 does your fiscal year start?

17 A Oh, I don't -- I guess January 1st to December 31st.

18 Q And what was the point of this email? What was -- what
19 were you trying to tell her with that?

20 A I was -- I saw a rolling -- a rolling average of what I
21 had spent for slings, and so I was kind of shocked by
22 that number. I can't remember what they cost, but that's
23 the equivalent of 100 -- probably 100 slings --
24 surgeries.

25 So I -- just like I don't count what -- what I've

1 been paid, I normally don't count how many slings that
2 I've done in a given year. And so this was toward the
3 end of the year, and it looks like I did 100 slings.

4 Q Okay. So if you had -- 100 slings in a year, is that a
5 lot?

6 A Yes.

7 Q What percentage of your -- of your practice would that
8 have made up for the year 2004?

9 A Oh, probably 20, 25 percent of -- of the female side that
10 I was doing either a prolapse -- a prolapse repair or
11 slings for incontinence.

12 Q And then if you'll look at the email right above that,
13 it's Lori Campbell responding to you directly on
14 November 15th of 2004; correct?

15 A Yes.

16 Q And if you look at that second paragraph, it says, "Yes,
17 you're one of our best customers," triple exclamation
18 mark. "Funny you should be looking at that today,"
19 period. "Erika and I were just reviewing preceptor
20 payout," period. "You've just about maxed out your
21 contract for the year," period.

22 Did I read that correctly?

23 A Yes.

24 Q And we talked earlier about the fact that your max amount
25 on your consulting agreement in 2004 was \$100,000; right?

1 A No.

2 Q Fair to say you haven't reviewed everything on your
3 reliance list?

4 A Yes.

5 Q What percentage of the documents on your reliance list
6 would you say you've reviewed?

7 A I can't give a percentage because a lot of these are
8 just -- are internal documents that I did not read, and
9 there's a lot of them.

10 Q Did you just -- did you not read the internal
11 documents -- the Ethicon internal documents?

12 A Very few of them. I just didn't find them relevant or
13 find anything in there that I could use.

14 Q And which of the depositions that -- looking at your list
15 of depositions, were there any in particular that you
16 remember reading that stood out to you?

17 A Well, I remember reading Ostergard, Margolis, Blaivis.

18 Q Any others?

19 A Moore.

20 Q Any others?

21 A In the past, Rosenzweig.

22 Q Any others?

23 A I don't recall any other.

24 Q Did you read any depositions of Ethicon employees?

25 A I did for the Perry trial. Not since.

1 opinions to a reasonable degree of medical certainty?

2 A Yes.

3 Q You don't hold yourself out to the community as a design
4 expert; is that fair?

5 A That is fair.

6 Q But are you an expert in urologic surgery?

7 A Yes.

8 Q And are you an expert in the materials used in urologic
9 surgery?

10 A Yes, I am.

11 Q And you don't hold yourself out to the community as a
12 warnings expert; correct?

13 A No, I don't.

14 Q But you've used a lot of medical devices throughout your
15 career?

16 A Yes.

17 Q Dozens, certainly?

18 A Yes.

19 Q Hundreds?

20 A Yes.

21 Q And before you use a medical device, you read the
22 instructions for use accompanying the device?

23 A I do.

24 Q And after treating patients with devices, you get a sense
25 of what sort of complications you see?

1 what is the standard of care.

2 Q And are there different levels of evidence?

3 A There is different levels of evidence. From the bottom,
4 which is anecdotal reporting, to the top, which is, say,
5 Cochrane review, meta-analysis, systematic reviews.

6 Q Where do internal company emails fall on the hierarchy of
7 levels of evidence?

8 A They don't fall at all, in any of it.

9 Q Where do failure modes and effects analyses fall in the
10 hierarchy of levels of evidence?

11 A They don't fall at all in the levels of evidence.

12 Q The opinions that you've expressed in your reports
13 regarding the safety and efficacy of the TVT, TVT-O, and
14 TVT slings, are those opinions based in part on your
15 education, including your medical school and residency?

16 A Yes.

17 Q Is it also based on continuing ed courses?

18 A Yes.

19 Q Are those opinions about the safety and efficacy of the
20 devices based on your clinical training and experience?

21 A Yes.

22 Q Are those opinions about the safety and efficacy of the
23 devices based on your review of the peer-reviewed
24 literature, book chapters, podium, and poster
25 presentations and abstracts?

1 reliance list?

2 A If it's alphabetically -- oh, yes. Yes.

3 Q And what date were those depositions taken?

4 A May 30th and 31st of 2013.

5 Q Have you -- is Dr. Weisberg's deposition from
6 November 12th and 13th of 2015 on your reliance list?

7 A No.

8 Q Are you aware that Dr. Weisberg was chosen by Ethicon to
9 testify as their corporate representative on the revised
10 TVT and Gynemesh IFUs?

11 A No, I was not aware.

12 Q Do you know he's Ethicon's medical director? Correct?

13 A Is he currently?

14 Q I believe so.

15 A I thought he was ten years ago.

16 Q Okay. Have you -- I'm assuming, given that it's not on
17 your reliance list, that you haven't reviewed that
18 deposition?

19 A No. Don't recall it.

20 Q And do you see Dr. Laura Angeleni's June 2015 deposition
21 on your reliance list?

22 A Yes. Did -- what was the date?

23 Q June of 2015.

24 A No.

25 Q Do you know that she's the -- she was the woman who